

## **REMARKS**

Favorable reconsideration is respectfully requested.

The claims are 15-32. New claims 30-32 are added.

New claims 30-32 are supported at page 4, lines 17-18 and at page 6, lines 12-14, of the specification.

No new matter is added.

### **Claim rejections 35 U.S.C. §103**

Claims 15-18, 22 to 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kim et al. (US 6,329,002) (hereinafter referred to as “Kim’002”) in view of Kim et al. (US 6,627,238) (hereinafter referred to as “Kim’238”).

Claims 15-29 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kim’002 in view of Kim’238, and further in view of Kodama et al. (US 2001/0044120).

Applicants respectfully traverse each of these rejections.

The present invention is based on the discovery that the product of a browning reaction of sugar and protein (i.e. a browning reaction product) is capable of effectively inhibiting urease, as an adhesin of *Helicobacter pylori*, from adhering to the gastric mucosa and thereby inhibiting *Helicobacter pylori* adhesion.

Kim’002 teaches a method of preventing and/or treating disorders associated with infection by *Helicobacter pylori* with nutritional food in combination with an active strain of a living organism. Kim’002 does not teach or suggest, or even mention, a browning reaction product as recited in claim 1. Accordingly, a food comprising a browning reaction product is not disclosed or suggested by Kim’002. Again, as discussed in the last reply, Kim’002 does not anywhere mention a toasted bagel.

Kim’238 teaches a browning composition for food having a dough crust. Kim’238 does not disclose or suggest, or anywhere mention, inhibiting *Helicobacter pylori* adhesion.

The prior art therefore does not teach or suggest methods of using a browning reaction product to inhibit *Helicobacter pylori* adhesion. There is nothing in the prior art to motivate one of ordinary skill in the art to combine the teachings of Kim'002 and Kim'238. The Office only argues that a toasted bagel and yogurt can be consumed together. However, the present invention is completely different from combining foods for eating as asserted by the Office. Applicants respectfully remind the Office that claims 15-21 of the present application are not product claims, but method claims. The Office does not provide the required "articulated reasoning with some rational underpinning" which explains why one of ordinary skill in the art would be motivated to combine the teachings of Kim'002 and Kim'238 with a reasonable expectation of success in inhibiting *Helicobacter pylori* adhesion. See MPEP §2142.

The Office alleges that "anyone who eats a toasted bagel with yogurt (which contains live strains of *Lactococcus sp.* HY 49 *Lactobacillus casei* HY 2782, and *Bifodobactedium longum* HY 8001), and drinks milk (which contains lactose and casein), reads on treating disorders associated with infection by *Helicobacter pylori*," as recited in the present claims. See Office Action, page 3, second paragraph. However the Office has misinterpreted the teachings of Kim'002, especially with respect to the above underlined parts. Kim'002 teaches a combination of living microorganisms, i.e., *Lastococcus sp.* HY 49, *Lactobacillus casei* HY 2782, and *Bifodobactedium longum* HY 8001 and nutritional food, i.e., yogurt, buttermilk, cream cheese, and ice cream. The basic premise of the Office's assertion is therefore incorrect.

The Office alleges that Kim'002 in claim 12 discloses that "the living organism being of lactic acid origin is selected from the group consisting of yogurt, buttermilk, cream cheese, and ice cream." See Office Action, page 3, second paragraph. However, it is described in claim 12 of Kim'002 that: "wherein said food is selected from the group consisting of a conventional food of lactic acid origin and a non-conventional food, said conventional food being selected from the group consisting of yogurt, buttermilk, cream cheese and ice cream." Kim '002, claim 12, does not disclose or suggest that the living organism, being of lactic acid origin, is selected from the group consisting of yogurt, buttermilk, cream cheese, and ice cream.

Kim'002 teaches at column 4, lines 17-24 (emphasis added):

. . . specific strains of non-toxic (to humans) live bacteria, by themselves, when maintained as ‘active strains’ in comestible foods, such as yogurt and other bacteria tolerant foods which may contain other living organisms, have the unique ability to imbue such foods with prophylactic and/or therapeutic properties because, it is hypothesized, active strains product bacteriocins which directly attach *H. pylori*.

Kim‘002 also describes that: “the food is fortified with an active strain selected from the group consisting of *Lactococcus sp.* HY 49, *Lactobacillus casei* HY 2782, and *Bifodobactedum longum* HY 8001.” See column 4, lines 42-45. It is thus clear from the description of Kim‘002 that the active strains are not naturally contained in the nutritional food, but are added to the nutritional food (i.e. yogurt, buttermilk, cream cheese, and ice cream). The specific living microorganisms *Lactococcus sp.* HY 49, *lactobacillus casei* HY 2782, and *Bifodobactedum longum* HY 8001, are not generally present in yogurt. According to Kim ‘002, living microorganisms (i.e., *Lasctococcus sp.* HY 49, *Lactobacillus casei* HY 2782, and *Bifodobactedum longum* HY 8001) cannot be selected from yogurt, buttermilk, cream cheese, and ice cream. The Office is therefore incorrect in alleging that “the living organism being of lactic acid origin is selected from the group consisting of yogurt, buttermilk, cream cheese, and ice cream.”

The rejection further asserts that:

Example 6 is used to ‘provide evidence that even the active strains, by themselves proved an unexpected prophylactic effect which is greatly improved by the addition of *H. pylori*-antibodies.’ For that reason, yogurt was used as a control in that example.

Office Action, page 6, first paragraph. However, the rejection does not consider the difference between sample 2 (yogurt and all three active strains), and the control (yogurt only) in the prophylactic effect which is clearly shown in Figure 1. Regardless of what Example 6 intends to demonstrate, the fact remains that yogurt is used as a control which does not have a prophylactic effect.

The rejection also asserts that: “it is the bagel that is being toasted, not the yogurt or cream cheese.” See Office Action, page 6, third paragraph. However, it is described in Kim‘002 that “[I]t is therefore a general object of this invention to provide a food for general human

consumption, comprising a food stored at a temperature in the range from about -45°C, but no more than 45°C.” See Kim ‘002, column 4, lines 37-40. That is, as the rejection has acknowledged, although yogurt is intended to be included as the nutritional food in Kim ‘002, a bagel is not intended to be included as the nutritional food in Kim ‘002.

Even if Kim ‘002 and Kim ‘238 are combined, the present invention could not be arrived at by one of ordinary skill in the art. A toasted bagel with yogurt or cream cheese does not contain 0.5% or more of a browning reaction product because the toasted bagel does not contain 0.5% or more of a browning reaction product, and yogurt or cream cheese does not contain a browning reaction product at all.

The Examiner alleges that “a bagel would contain sugar D-glucose” and that “casein is the predominant phosphoprotein that accounts for nearly 80% of proteins in milk and cheese, and lactose is a sugar which is found most notably in milk.” See Office Action, page 78, first paragraph.

However, *Helicobacter pylori* adhesion cannot be inhibited by consuming a toasted bagel with yogurt or cream cheese, because the yogurt or cream cheese does not contain the active ingredient for inhibiting *Helicobacter pylori* in Kim ‘002, i.e., *Latococcus sp.* HY 49, *Lactobacillus casei* HY 2782 and *bifodobatedum longum* HY 8001. Also, a toasted bagel does not contain enough browning reaction product to inhibit *Helicobacter pylori* adhesion.

The Examiner further alleges that:

. . . since the bagel/yogurt, and milk consumption varies according to people’s appetite, age, and weight, the amount of browning reaction product as claimed is a result-effective adjustment in conventional working parameter, which is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Office Action, page 8, second paragraph.

However, one of ordinary skill in the art would not recognize that the browning reaction product is known to be effective to inhibit *Helicobacter pylori* in the first instance. Since the prior art does not teach or suggest that the browning reaction product inhibits *Helicobacter pylori* adhesion, one of ordinary skill in the art would have no motivation or suggestion to additionally

incorporate the browning reaction product into food with a reasonable expectation of success in inhibiting *Helicobacter pylori* adhesion. One of ordinary skill in the art who was familiar with Kim '002 and Kim '238 would have, at most, a suggestion to additionally incorporate the living organisms, *Lactococcus sp.* HY 49, *Lactobacillus casei* HY 2782, and *Bifidobacterium longum* HY 8001, into food to inhibit *Helicobacter pylori* adhesion.

The rejection's argument can be summarized as follows.

- (i) Substances A, B and C were known substances. It was known that substance A in combination with substance B has a medical activity X.
- (ii) An inventor found that substance C has a medical activity X as well.
- (iii) Since substances A, B and C can be consumed together, the invention based on the finding (ii) above is obvious.

However, using the above summarized argument, any invention directed to a novel activity of a known substance contained in food could be found obvious. This is because most of the medicines are administered before, during, or after the eating of food.

The presently claimed combination of elements to make a new invention is completely different from combining foods to eat. The Office has taken the position that people usually consume the browning reaction product with a known *Helicobacter pylori* inhibitor. However, since claims 15-21 of the present application are not product claims but method claims, the Office has not established obviousness of the presently claimed invention.

The proper question is whether it is obvious or not to administer a browning reaction product to inhibit *Helicobacter pylori* adhesion. Since the prior art does not teach or suggest the claimed activity of a browning reaction product in inhibiting *Helicobacter pylori* adhesion, there is nothing in the prior art which would provide a suggestion or motivation to one of ordinary skill in the art to combine the teachings of Kim '002 and Kim '238 with a reasonable expectation of success in inhibiting *Helicobacter pylori* adhesion. Accordingly, the pending prior art rejections must be withdrawn.

### **New claims 30-32**

The browning reaction product of new claims 30-32 is obtained, as defined in the specification on page 6, second full paragraph, by mixing sugars and proteins and heating the mixture in a neutral aqueous solution. When the browning reaction is carried out in a neutral aqueous solution, the reaction temperature is preferably at least 100°C, and particularly preferably at least 120°C. See page 6, lines 12-14 of the present specification. One cannot make browning reaction product by consuming sugars and proteins together. That is, people who consume a toasted bagel with yogurt would not be administered a food to which 0.5% by mass or more product of browning reaction product is incorporated, as recited in claims 30-32.

Thus, when “it is the bagel that is being toasted, not the yogurt or cream cheese” as the Examiner states (page 6, third paragraph), the food comprising 0.5% by mass or more product of browning reaction product would not be present.

Accordingly, new claims 30-32 are clearly allowable over the prior art.

**Conclusion**

No further issues remaining. Allowance of the application is respectfully requested.

If the Examiner has any comments or proposals for expediting the prosecution, please contact the undersigned at the telephone number below.

Respectfully submitted,

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